3.2 Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Steve Singlar Regulatory Submissions Manager Philips Ultrasound MS 0135 3000 Minuteman Road Andover, MA 01810

Tel: (978) 659-2101 Fax: (978) 975-7324

This summary was prepared on November 12, 2004.

The proprietary name of the device is the HD11 Diagnostic Ultrasound System. In combination with the transducers listed in the Indications for use tables are commonly known as a diagnostic ultrasound system and transducers.

These devices are classified as follows:

90IYN Ultrasonic Pulsed Doppler Imaging System 90IYO Ultrasonic Pulsed Echo Imaging System 90ITX Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

The HD11 is a diagnostic ultrasound device. It consists of a system console containing the power supply and electronic circuitry required to generate the image, a display screen and a connection to the separate transducers. It is substantially equivalent to other ultrasound systems including the Philips M2540A EnVisor and HDI-5000 series Ultrasound systems with transducers.

The 3D8-4 and L15-7io transducers are substantially equivalent to other Philips sector, linear and endo-cavity ultrasound transducers.

The HD11 system and transducers function in a manner identical to all ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo-electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The differing acoustic properties of the tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this system process the Doppler shift frequencies from the echoes of moving targets (such as blood), to detect and graphically display the Doppler shifts of these tissues as flow.

The HD11 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The HD11 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate device and the HD11 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and the HD11 have the same gray-scale and Doppler capabilities.
- Both the predicate device and the HD11 use essentially the same technologies for imaging,
 Doppler functions and signal processing.
- Both the predicate device and the HD11 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate device and the HD11 are manufactured under equivalent quality systems.
- Both the predicate device and the HD11 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and HD11 are designed and manufactured to the same electrical and physical safety standards.

Food and Drug Administration



9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2005

Philips Ultrasound % Ms. Laura Danielson Responsible Third Party Official TÜV Product Service 1775 Old Highway 8 NEW BRIGHTON MN 55112-1891

Re: K043535

Trade Name: HD11 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: December 11, 2004 Received: December 22, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HD11 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S3-1 (21711A) Sector Transducer S4-2 (989605344981) Sector Transducer PA 4-2 (21422A) Sector Transducer

S8-3 (21750A) Sector Transducer S12-4 (21780A) Sector Transducer T6H (21378A) Omni III Transesophagel Transducer S7-20mni (21778A) Omni III Sector Transducer S7-3t (21781A) Minimulti Sector Transducer D2cwc (4000-0947-01) 1.9 MHz non-imaging Pencil Probe D5cwc (4000-0950-01) 5.0 MHZ non-imaging Pencil Probe D2tcd (8500-1860-01) 2.0 MHz non-imaging Pencil Probe C8-5 (8500-1664-01) Curved Linear Transducer C5-2 (21426A) Curved Linear Transducer C9-4 (8500-1658-01) Curved Linear Transducer C8-4v (21437A) Curved Linear Transducer C9-5ec (8500-1655-01) Endocavity Transducer L12-5 (8500-1660-01) Linear Transducer L12-3 (21475A0 Linear Transducer L8-4 (8500-1659-01) Linear Transducer L15-7io (989605341571) Linear Intra-operative Transducer 3D8-4 (989605345331) Curved Linear Transducer 3D6-2 (8500-2023-01) Curved Linear Transducer 3D9-3V (8500-1715-01) Curved Linear Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Sam a. Logram
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

4.3.2 Indications for Use Tables

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic	N		N	N	N	N	N	
	Fetal	N	N	N	N	N	N	N	
	Abdominal	N	N	N	N	N	N	N	
	Intra-operative	N	N	N	N	N	N	N	
	(Epicardial/Vascular)								
	Intra-operative (Neuro)	N	N	N		N	N	N	
	Laparoscopic			<u> </u>					
Fetal Imaging	Pediatric	N	N	N	N	N	N	N	
& Other	Small Organ (Thyroid,	N	.N	N	ł	N	N	N	
· <u>-</u>	Scrotum, Breast)								
ė	Neonatal Cephalic	Ŋ	N	N	N	N·	. N	N ·	
	Adult Cephalic	N	N	N	N	N	N	N	
:	Trans-rectal	N	N	N		N	N	N	
	Trans-vaginal	N	N	N		N	N	N	
	Trans-urethral								
	Trans-esoph. (non-Card.)		<u></u>						
	Intra-luminal			<u> </u>					
	Other (Gynecological)	N	N	N	N	N	N	N	
	Cardiac Adult	N	N	N	N	N	N	N	
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N	
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	
	Other (Fetal)	N	N	N		N	N	N	
Peripheral	Peripheral vessel	N	N	N	N	N	N	N	
Vessel	Other (Carotid, I/O)	N	N	N		N	N	N	
	Musculo-skel (conventional)	N	N	N		N	N	N	
	Musculo-skel (superficial)	N	N	N		N	N	N	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D/4-D Imaging, Directional Angio Imaging, Tissue Doppler Imaging, 4D Fetal Heart, STIC (Spatial Temporal Image Correlation), SonoCT, X-Res, IMT Measures, iSCAN, 2D Doppler, Color Power Angio.

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual Mode,

Previous submission: None

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

51 (k) Number __

510(k	() N	√umber: <u>K</u>
Syste	m:	Philips Ultrasound HD11 Diagnostic Ultrasound System
	_	

Transducer: S3-1 (21711A) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic				į			1		
	Fetal	N	N	N	N	N	N	N		
	Abdominal	N	N	N	N	N	N	N		
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal Imaging	Pediatric	N	N	N	N	N	N	N		
& Other	Small Organ (Scrotum, Thyroid, Breast)						i			
* * * *	Neonatal Cephalic			ļ			1			
i .	Adult Cephalic	N·	N	N	N	N	N	N		
	Trans-rectal						1			
-	Trans-vaginal	1								
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Intra-luminal				}					
	Other (Gynecological)									
	Cardiac Adult	·N	N	N	N	N	N	N		
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N		
	Trans-esoph. (Cardiac)									
	Other (Specify)									
Peripheral	Peripheral vessel									
Vessel	Other (Carotid)									
	Musculo-skel (conventional)									
	Musculo-skel (superficial)							<u> </u>		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: X-Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Freehand Imaging, Directional Angio
Imaging, Tissue Doppler Imaging, Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

Previous submission: Cleared in K030455

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number _____ K0435

510(k) Number:	<u>K</u>
System: Philips	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	S4-2 (989605344981) Sector Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic	N		N	N	N	N	N		
	Fetal	N	N	N	N	N	. N	N		
	Abdominal	N	N	N	N	N	N	N		
	Intra-operative (Specify)				-					
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal Imaging	Pediatric	N	N	N	N	N	N	N		
& Other	Small Organ (Scrotum, Thyroid, Breast)						į			
1	Neonatal Cephalic	ļ	J.,				1	. •		
•	Adult Cephalic	N	N	N	N	N	N	N		
	Trans-rectal	1		i	7					
	Trans-vaginal									
	Trans-urethral			<u> </u>				•,•		
	Trans-esoph. (non-Card.)		1				-			
	Intra-luminal					**				
	Other (Gynecological) GYN	N	N	N	N	N	N	N		
	Cardiac Adult	N	N	N	N	N·	N	N		
Cardiac	Cardiac Pediatric	N	N	N	N	N	N -	N		
	Trans-esoph. (Cardiac)				-					
	Other (Specify)				•					
Peripheral	Peripheral vessel	N	N	N	N	N	N	N		
Vessel	Other (Carotid)									
	Musculo-skel (conventional)									
	. Musculo-skel (superficial)		ļ .							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging,
Tissue Doppler Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

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Prescription Use (Per 21 CFR 801.109)

Previous submission: Cleared as PA4-2 in K014191

(Division Sign-Off)

Obvision of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

510(k) Number:	
System: Philips	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	PA 4-2 (21422A) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined	Other*	
(Track I Only)	(Tracks I & III)		ļ			Doppler	(Specify)	(Specify)	
Ophthalmic	Ophthalmic	N	<u> </u>	N	N	N	N	N	
	Fetal	N	N	N	N	N	N	N	
	Abdominal	N	N	N	N	N	N	N	
	Intra-operative (Specify)	L	<u> </u>						
,	Intra-operative (Neuro)	<u> </u>	<u> </u>		ļ				
	Laparoscopic		<u></u>						
Fetal Imaging	Pediatric	N	N	N	N	N	N	N	
& Other	Small Organ (Scrotum,	1							
ł	Thyroid, Breast)	!	ļ					i	
ļ	Neonatal Cephalic	<u> </u>		!			<u> </u>		
	Adult Cephalic	N	N	N	N	N	N	N	
}	Trans-rectal	 	ļ. <u>.</u>		ļ	ļ			
	Trans-vaginal		ļ	ļ				ļ	
	Trans-urethral	ļ	ļ	ļ					
	Trans-esoph. (non-Card.)	ļ		!					
<u>,</u>	Intra-luminal			ļ					
	Other (Gynecological)	N	N	N	N	N	N	N	
	Cardiac Adult	N	N	N	N	N	N	N	
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N	
	Trans-esoph. (Cardiac)		ļ	ļ		ļ		ļ	
	Other (Specify)							-	
Peripheral	Peripheral vessel	<u> </u>	1	ļ		ļ		<u> </u>	
Vessel	Other (Carotid)	<u> </u>	ļ	<u> </u>	ļ			ļ	
	Musculo-skel (conventional)		<u> </u>	ļ	 			<u> </u>	
1	Musculo-skel (superficial)				<u> </u>	<u></u>		<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X-Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging,
Tissue Doppler Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: K014191

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,

and Radiological Devices
61/3k/ Mumber

K04333

510(k) Number: <u>K</u>

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: S8-3 (21750A) Sector Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic									
	Fetal	N	N	N		N	N	N		
	Abdominal	N	N	N	N	N	N	N		
	Intra-operative (Specify)									
	Intra-operative (Neuro)					-				
	Laparoscopic				-					
Fetal Imaging	Pediatric	N	N	N	N	N	N	N		
& Other	Small Organ (Scrotum, Thyroid, Breast)		-, -	·			1			
	Neonatal Cephalic	' N ·	N	N	. N .	N	N	N		
	Adult Cephalic									
	Trans-rectal							-		
	Trans-vaginal									
	Trans-urethral				· -					
	Trans-esoph. (non-Card.)									
	Intra-luminal									
	Other (Gynecological)	N	N	N	N	N	N	N		
,,	Cardiac Adult	N	N	N	N	N	N	N		
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N		
	Trans-esoph. (Cardiac)									
	Other (Fetal Heart)	N	N	N	N	N	N	N		
Peripheral	Peripheral vessel	N	N	N	N	N	N	N		
Vessel	Other (Carotid)							-1		
	Musculo-skel (conventional)									
	Musculo-skel (superficial)						····			

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X-res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Tissue Doppler Imaging, Color Power
Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: Cleared as \$8 (21350A) in K014191

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: S12-4 (21780A) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica	tion	Mod	e of Op	peration				
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)	<u> </u>				Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic	<u> </u>						
	Fetal							
	Abdominal							
	Intra-operative (Cardiac)	N	N	N	N	N	N	N
	Intra-operative (Neuro)	<u> </u>						
	Laparoscopic]				•		
Fetal Imaging	Pediatric	N	N	N	N	N	N	N
& Other	Small Organ (Scrotum,							
	Thyroid, Breast)	<u> </u>	ļ				1	
	Neonatal Cephalic	N	N	N	N	N	! N	: N
	Adult Cephalic							İ
	Trans-rectal	1						ļ
	Trans-vaginal	<u> </u>			<u> </u>			·
ł	Trans-urethral	1	ļ					
	Trans-esoph. (non-Card.)	1	<u> </u>					1
	Intra-luminal							
	Other (Gynecological)	<u> </u>		<u> </u>			<u> </u>	
	Cardiac Adult	N	N	· N	N	N	N	N
Cardiac	Cardiac Pediatric	N	N	·N	N	N	N	N
	Trans-esoph. (Cardiac)	<u></u>	ļ	·				
	Other (Specify)	<u> </u>			<u> </u>			<u> </u>
Peripheral	Peripheral vessel	N	N	N	N	N	N	N
Vessel	Other (Carotid)							
1	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Tissue Doppler Imaging, Color
Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: Cleared as s12 (21380A) in K014191, K971116

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices KOH3595
610(k) Number

System: Philips (litrasound HDH Diagnostic U	ltrasoun	a Syste	m							
Transducer:	T6H (21378A) Omni III Trai										
Intended Use: Dia	ignostic ultrasound imaging or	fluid flo	w anal	ysis of th	e human b	ody as follo	ws:				
Clinical Applicati	on	Mod	Mode of Operation								
General	Specific	В	М	PWD	CWD	Color	Combined	Other*			
(Track I Only)	(Tracks I & III)			1		Doppler	(Specify)	(Specify)			
Ophthalmic	Ophthalmic										
	Fetal	7									
	Abdominal										
	Intra-operative (Specify)			,							
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal Imaging	Pediatric				7.7						
& Other	Small Organ (Scrotum,										
	Thyroid, Breast)		ļ								
	Neonatal Cephalic						1	ें देहिंसा			
	Adult Cephalic							· ·			
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral					· -					
	Trans-esoph. (non-Card.)						·				
	Intra-luminal										
	Other (Gynecological)							-			
	Cardiac Adult	N	N	N	N	N	N	· N			
Cardiac	Cardiac Pediatric	Ν.	N	N	N	N	N	N			
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: X-Res, Angio, , Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Tissue Doppler Imaging

Combined modes: Duplex = 2D + Doppler, Triplex = 2D + Doppler + Color, Dual

Previous submission: K014191, K022303

Peripheral

Vessel

Other (Specify)

Peripheral vessel

Musculo-skel (conventional)
Musculo-skel (superficial)

Other (Carotid)

510(k) Number: K

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510th Number ___

510(k) Number:	K
System: Philips	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	S7-20mni (21778A) Omni III Sector transducer
	igamostic ultrasound imaging or fluid flow analysis of the human body as follow

Clinical Applicat	ion	Mode of Operation									
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)			
Ophthalmic	Ophthalmic										
	Fetal	<u> </u>				<u> </u>					
	Abdominal	<u> </u>									
	Intra-operative (Specify)					<u></u>					
	Intra-operative (Neuro)					<u> </u>					
	Laparoscopic					!					
Fetal Imaging	Pediatric		ļ	ļ							
& Other	Small Organ (Scrotum,										
	Thyroid, Breast)	<u> </u>	 	ļ	ļ	<u>_</u>	·	4 10			
eg d	Neonatal Cephalic		<u> </u>	ļ				7 5 54			
	Adult Cephalic	<u> </u>	<u> </u>					-			
	Trans-rectal		ļ	ļ		<u> </u>					
	Trans-vaginal	1	ļ			!					
	Trans-urethral	_	ļ	ļ		ļ		-			
	Trans-esoph. (non-Card.)	<u>.</u>				 					
• ••	Intra-luminal	↓	↓			· .	ļ				
	Other (Gynecological)	<u> </u>				<u> </u>					
	Cardiac Adult	N	N	N	N	N	. N	N			
Cardiac	Cardiac Pediatric	N	N	N	N	N	. N	N:			
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N ·			
	Other (Specify)	<u> </u>						<u> </u>			
Peripheral	Peripheral vessel		<u> </u>			<u> </u>		<u> </u>			
Vessel	Other (Carotid)					ļ <u> </u>	;	ļ			
	Musculo-skel (conventional)					<u> </u>	<u> </u>	<u> </u>			
	Musculo-skel (superficial)	1	1				1	1			

WithSchio-sker (superinolar)
N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X-Res, Angio, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Tissue Doppler
Imaging, Dual, Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: Cleared as 21378A in K022303

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices KD 4 35 35

510(k) Number: K

System: Philips Ultrasound HD11 Diagnostic Ultrasound System Transducer: S7-3t (21781A) Minimulti Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica	tion	Mode of Operation									
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)			
Ophthalmic	Ophthalmic					<u>"</u>					
	Fetal										
	Abdominal			I							
	Intra-operative (Specify)										
	Intra-operative (Neuro)		}								
	Laparoscopic										
Fetal Imaging	Pediatric										
& Other	Small Organ (Scrotum,			Ī .		***	*				
	Thyroid, Breast)	<u> </u>	<u> </u>	ي	<u> </u>	<u> </u>					
-	Neonatal Cephalic ':			ļ . 1			2				
	Adult Cephalic										
_	Trans-rectal	<u> </u>									
	Trans-vaginal	<u> </u>									
	Trans-urethral										
	Trans-esoph. (non-Card.)	·									
	·Intra-luminal			1							
	Other (Gynecological)										
	Cardiac Adult	N	N	N	N	N	N	N			
Cardiac	Cardiac Pediatric	N	N	N	·N	N	N	N.			
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N			
	Other (Specify)										
Peripheral	Peripheral vessel	1									
Vessel	Other (Carotid)							1			
	Musculo-skel (conventional)										
	Musculo-skel (superficial)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: X-Res, Angio, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Tissue Doppler
Imaging, Color Power Angio.
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: None

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Padiological Devices,

511 (Kr. Wurnber ___

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: D2cwc (4000-0947-01) 1.9MHz non-imaging Pencil Probe
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)			
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Scrotum, Thyroid, Breast) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Intra-luminal Other (Gynecological)										
Cardiac Peripheral	Cardiac Adult Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify) Peripheral vessel				N N						
Vessel	Other (Carotid) Musculo-skel (conventional) Musculo-skel (superficial)										

N= new indication; P= previously cleared by FDA; E= added under Appendix	(E
*Other modes: None	
Combined modes: None	
Previous submission: Cleared as 21221B in K014191	

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

K043535

Clinical Applicat		fluid flow analysis of the human body as follows: Mode of Operation									
General	Specific	В	M	PWD	CWD	Color	Combined	Other*			
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)			
Ophthalmic	Ophthalmic							(-1))			
	Fetal										
	Abdominal	1				1-12-					
•	Intra-operative (Specify)	1						· -			
	Intra-operative (Neuro)		İ								
	Laparoscopic										
Fetal Imaging	Pediatric	1									
& Other	Small Organ (Scrotum,										
	Thyroid, Breast)			l							
	Neonatal Cephalic						. •				
	Adult Cephalic			•			:				
· · · · · · · · · · · · · · · · · · ·	Trans-rectal •							l- cre			
	Trans-vaginal						····				
	Trans-urethral										
	Trans-esoph. (non-Card.)						-				
	Intra-luminal							T-1-1-			
	Other (Gynecological)										
,	Cardiac Adult							· · · · · · · · · · · · · · · · · · ·			
Cardiac	Cardiac Pediatric										
	Trans-esoph. (Cardiac)							·			
· 	Other (Specify)										
Peripheral	Peripheral vessel			N	N			· ·			
Vessel	Other (Carotid)					*					
	Musculo-skel (conventional)				_ "			·			
	Musculo-skel (superficial)					· -					
N= new indicatio	n; P= previously cleared by FDA	; E= ad	ded un	der Appe	ndix E	<u></u>					
*Other modes: N	one	•									
Combined modes	: None										
Previous submiss	ion: Cleared as 21223B in K014	101									

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

KOH3535

510(k) Number: <u>I</u>										
	Iltrasound HD11 Diagnostic Ult									
	D2tcd (8500-1860-01) 2.0MHz									
·	agnostic ultrasound imaging or f	*		*	e human b	ody as follow	vs:			
Clinical Applicati		}	Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined	Other*		
(Track I Only)	(Tracks I & III)	<u> </u>				Doppler	(Specify)	(Specify)		
Ophthalmic	Ophthalmic			<u> </u>						
	Fetal		<u> </u>							
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
*	Laparoscopic									
Fetal Imaging	Pediatric									
& Other	Small Organ (Scrotum,	•								
	Thyroid, Breast)									
	Neonatal Cephalic									
	Adult Cephalic			N			-			
	Trans-rectal				i.			¥,44,		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Intra-luminal									
	Other (Gynecological)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric							•		
	Trans-esoph. (Cardiac)									
, I	Other (Specify)									
Peripheral	Peripheral vessel			N			·			
Vessel	Other (Carotid)									
	Musculo-skel (conventional)									
	Musculo-skel (superficial)						· · · · · · · · · · · · · · · · · · ·			
N= new indication	n; P= previously cleared by FDA	; E= ad	ded ur	ıder Appe	ndix E					
*Other modes: N		•								

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Prescription Use (Per 21 CFR 801.109)

Previous submission: Cleared as D2TC in K030455

Combined modes: None

(Division Sign-Off)
Division of Reproductive, Abdominal, and Parioterical Devices
6) and Manner

510(k) Number	: <u>K</u>
System: Philips	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	C8-5 (8500-1664-01) Curved Linear Transducer
Intended Use: I	Diagnostic ultrasound imaging or fluid flow analysis of the human body a

Clinical Application	ı	Mod	e of Op	peration				
	Specific Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic (Ophthalmic							- 7/
F	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
I	ntra-operative (Specify)							
I	ntra-operative (Neuro)							
I	aparoscopic						-	
Fetal Imaging P	Pediatric	N	N	N		N	N	N
	Small Organ (Scrotum,							
	Thyroid, Breast)							
	Neonatal Cephalic	N	N	N	-	N'	- N	N
	Adult Cephalic					•		1.34
1	rans-rectal		<u> </u>					
Ţ	Trans-vaginal							
· · ·	rans-urethral							
	Trans-esoph. (non-Card.)							
· · · · · · · · · · · · · · · · · · ·	ntra-luminal							
C	Other (Gynecological)	N	·N	N		N	N	N·
C	Cardiac Adult				-			
Cardiac C	Cardiac Pediatric							
T	rans-esoph. (Cardiac)							
C	Other (Fetal)	N	· N	N	<u> </u>	N	N	N.
Peripheral . P	eripheral vessel	N	: N	N .		N	N	N .
Vessel C	Other (Carotid)	~			-			
N	Ausculo-skel (conventional)							
·	Ausculo-skel (superficial)							·-

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, iSCAN, Doppler/2D, Color Power Angio

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

Previous submission: Cleared on K030455

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Tadiological Devices,

うこと Number __

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: C5-2 (21426A) Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion	Mode	e of Op	eration				
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N
•	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							ļ
Fetal Imaging	Pediatric	N	N	N		N	N	N
& Other	Small Organ (Scrotum, Thyroid, Breast)	N	N	N	ļ .	N	N	N
	Neonatal Cephalic							
• • • • • • • • • • • • • • • • • • • •	Adult Cephalic				·			. 3
1	Trans-rectal				1			i i i i geg
	Trans-vaginal							-
	Trans-urethral							·
	Trans-esoph. (non-Card.)							<u> </u>
	Intra-luminal			·				
	Other (Gynecological)	N	N	N		N	N	N
	Cardiac Adult					<u> </u>		
Cardiac	Cardiac Pediatric			<u> </u>				
•	Trans-esoph. (Cardiac)	<u> </u>	<u> </u>	<u> </u>			<u> </u>	ļ <u>.</u>
	Other (Specify)	L	<u> </u>	<u> </u>				
Peripheral	Peripheral vessel	N	N	N		N	N	N
Vessel	Other (Carotid)	1					•	
	Musculo-skel (conventional)		↓		ļ			
	Musculo-skel (superficial)			<u> </u>		<u> </u>		

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: C9-4 (8500-1658-01) Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic							(-[
	Fetal	N	N	N		N	N	N		
	Abdominal	N	N	N		N	N	N		
	Intra-operative (Specify)				1					
	Intra-operative (Neuro)									
	Laparoscopic	1				<u> </u>				
Fetal Imaging	Pediatric	N	N	N	1	N	N	N		
& Other	Small Organ (Scrotum,							·		
	Thyroid, Breast)									
	Neonatal Cephalic						• • •			
	Adult Cephalic						. ((A.4)		
,	Trans-rectal :						,	1 11,000		
	Trans-vaginal							•		
	Trans-urethral									
	Trans-esoph. (non-Card.)									
•	Intra-luminal									
	Other (Gynecological)	N	N	N		N	N	N		
	Cardiac Adult				_					
Cardiac	Cardiac Pediatric									
:	Trans-esoph. (Cardiac)									
	Other (Fetal)	N	N	N		N	N	N		
Peripheral	Peripheral vessel	N	N	N		N	N.	N		
Veșsel	Other (Carotid)									
	Musculo-skel (conventional)									
	Musculo-skel (superficial)					•				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging., Color Power Angio Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

Previous submission: Cleared on K030455

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)4

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: C8-4v (21437A) Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	tion	Mod	e of Op	ocration				
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)			<u> </u>				
	Laparoscopic							
Fetal Imaging	Pediatric			ļ				
& Other	Small Organ (Scrotum,				Ì			1
n.	Thyroid, Breast)		<u> </u>	ļ		-		
	Neonatal Cephalic		ļ. <u> </u>	<u> </u>				
	Adult Cephalic	<u> </u>	ļ			}	:	1.000
	Trans-rectal	<u> </u>	ļ			ļ		
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral					ļ		
	Trans-esoph. (non-Card.)	!		1	ļ	ļ		
	Intra-luminal	ļ	<u> </u>		<u> </u>	<u> </u>	1	•
	Other (Gynecological)	ļ	<u> </u>		<u> </u>	ļ	 :	ļ
	Cardiac Adult	<u>. </u>	ļ	1		<u> </u>		<u> </u>
Cardiac	Cardiac Pediatric		<u> </u>					<u> </u>
	Trans-esoph. (Cardiac)				ļ	ļ	ļ	
	Other (Specify)	<u> </u>				<u> </u>	-	
Peripheral	Peripheral vessel		<u> </u>			1		<u> </u>
Vessel	Other (Carotid)			1				
	Musculo-skel (conventional)	1				<u> </u>		
	Musculo-skel (superficial)	L						

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: K014191

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _____

510(k) Number: <u>K</u>
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: C9-5ec (8500-1655-01) Endocavity Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica	tion	Mode of Operation									
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)			
Ophthalmic	Ophthalmic										
	Fetal	N	N	N		N	N	N			
	Abdominal	Í									
	Intra-operative (Specify)					***	***				
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal Imaging	Pediatric				-						
& Other	Small Organ (Scrotum,										
	Thyroid, Breast)		1	:							
_	Neonatal Cephalic				şa. 4						
	Adult Cephalic	ŀ						. 3 N. S. S.			
*	Trans-rectal	N	Įų	N		N	N	Ň			
	Trans-vaginal	N	N	N		N	N	N			
	Trans-urethral										
	Trans-esoph. (non-Card.)		-								
	Intra-luminal										
	Other (Gynecological)	N	N	N		N	N	N			
	Cardiac Adult										
Cardiac	Cardiac Pediatric					·					
	Trans-esoph. (Cardiac)										
	Other (Specify)										
Peripheral	Peripheral vessel										
Vessel	Other (Carotid)						-	-			
	Musculo-skel (conventional)										
	Musculo-skel (superficial)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D freehand Imaging, Directional Angio Imaging, Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

Previous submission: Cleared on K030455

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number ____

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: L12-5 (8500-1660-01) Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion	Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
1	Intra-operative (Neuro)							
	Laparoscopic							
Fetal Imaging	Pediatric	N	N	N	<u> </u>	N	N	N
& Other	Small Organ (Scrotum, Thyroid, Breast)	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal				<u> </u>			1/3 /
	Trans-vaginal							
	Trans-urethral						;	
	Trans-esoph. (non-Card.)							
	Intra-luminal	<u> </u>						
1	Other (Gynecological)	<u> </u>			<u> </u>			
	Cardiac Adult				ļ		î	
Cardiac	Cardiac Pediatric			ļ			,	
	Trans-esoph. (Cardiac)					1		
	Other (Specify)							-
Peripheral	Peripheral vessel	N	Ŋ	N		N	N	N
Vessel	Other (Carotid)	N	N	N		N	N	N
	Musculo-skel (conventional)	N	N	N		. N	N	N
	Musculo-skel (superficial)	N	N	N		N _	N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, IMT measures,	, Color Power
Angio	* * * #
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: Cleared in K030455	

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

LO43535

510(k) Number:		
System: Philips	s Ultrasound HD11 Diagnostic Ultrasour	ıd System

Transducer: L12-3 (21475A) Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	N	N	N		N	N	N		
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic						·			
Fetal Imaging	Pediatric	N	N	N		N	N	N		
& Other	Small Organ (Scrotum,	N	N	N	1	N	N	N		
,	Thyroid, Breast)									
	Neonatal Cephalic			<u> </u>		•	<u>.</u> :	₹5¢a		
	Adult Cephalic						,	\$7.5a		
	Trans-rectal									
1	Trans-vaginal		<u></u>	ļ			:	3. 3.		
	Trans-urethral			<u> </u>			<u></u>			
	Trans-esoph. (non-Card.)				<u> </u>					
	Intra-luminal		٠.					<u> </u>		
rape redemandration in the second	Other (Gynecological)		ŀ					<u> </u>		
	Cardiac Adult			*			<u> </u>			
Cardiac	Cardiac Pediatric									
ar, e "=	Trans-esoph. (Cardiac)									
and the company of the company	Other (Specify)									
Peripheral	Peripheral vessel	N	N	N		N	N	N		
Vessel	Other (Carotid)	N	N	N		N	N	N_		
	Musculo-skel (conventional)	N	N	N		N	N	N		
	Musculo-skel (superficial)	N	N	N		N	N	N		

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio	
Imaging, IMT Measures, Color Power Angio	
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: K014191	

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

K043532

510(k) Number: K
System: Philips Ultrasound HD11 Diagnostic Ultrasound System
Transducer: L8-4 (8500-1659-01) Liner Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)		
Ophthalmic	Ophthalmic	<u> </u>								
	Fetal Abdominal	N	N	N		N	N	N		
	Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic									
Fetal Imaging	Pediatric	N	N	N	İ	N	N	N		
& Other	Small Organ (Scrotum, Thyroid, Breast)	N	N	N		N	N	N		
	Neonatal Cephalic							4 2		
	Adult Cephalic							1 8 3 6		
	Trans-rectal			ļ <u>.</u>		ļ		1 1 1 1 1 1 1 1 1		
•	Trans-vaginal									
	Trans-urethral	<u> </u>			<u> </u>		1			
	Trans-esoph. (non-Card.)							:		
	Intra-luminal	İ		ļ						
	Other (Gynecological)	<u> </u>				<u> </u>				
	Cardiac Adult	<u> </u>	<u></u>							
Cardiac	Cardiac Pediatric	<u> </u>	ļ	<u> </u>	<u> </u>	1				
,	Trans-esoph. (Cardiac)							<u> </u>		
	Other (Specify)	ļ.,					,			
Peripheral	Peripheral vessel	N	N	N		· N	∴ N	N		
Vessel	Other (Carotid)	N	N	N		N	N	N ·		
	Musculo-skel (conventional)	N	N	N		N	N	N		
	Musculo-skel (superficial)	N	N	N		N	N	N		

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio
Imaging, IMT, Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual
Previous submission: Cleared on K030455

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ____

K043535

		agnostic ultrasound imagir					ody as follo	ws:	
	Clinical Applicat				peration				
	General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	(S
ļ	Ophthalmic	Ophthalmic							(5

510(k) Number: K

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Clinical Applica	tion	Mod	le of O _l	peration				
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							<u> </u>
	Fetal							 -
l	Abdominal							
	Intra-operative (Cardiac, Vascular)	N	N	N	f	N	N	N
1	Intra-operative (Neuro)	N	N	N		N	N	N
	Laparoscopic							
Fetal Imaging	Pediatric	N	N	N	, <u>.</u>	N	N	N
& Other	Small Organ (Scrotum, Thyroid, Breast)	N	N	N		N	N	N
	Neonatal Cephalic							*
	Adult Cephalic							1 1 1 1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							-
_	Trans-esoph. (non-Card.)	<u> </u>						-
And the second second	Intra-luminal	<u> </u>		-				
	Other (Gynecological)							
	Cardiac Adult	I						
Cardiac	Cardiac Pediatric				-			* -
	Trans-esoph. (Cardiac)							, , , , , , , , , , , , , , , , , , , ,
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N		N	N	N
Vessel	Other (I/O)	N	N	N		N	N	N
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)	N	N	N		N	N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: SonoCT, X-Res, Angio, Panoramic, 3-D Imaging, Directional Angio Imaging,	·r
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual	
Previous submission: Cleared K030455	

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _

510(k) Number:	<u>K</u>
System: Philips	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	3D8-4 (989605345331) Curved Linear Transducer
Intended Use: D	iagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion	Mode	of Op	eration			····	
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)		ļ		ļ	ļ		
	Intra-operative (Neuro)			ļ				
	Laparoscopic							<u> </u>
Fetal Imaging	Pediatric	N	N	N		N	N	N
& Other	Small Organ (Scrotum,					ļ		
	Thyroid, Breast)		ļ	ļ <u>.</u>		<u> </u>		ļ
	Neonatal Cephalic	ļ					,	
. 3	Adult Cephalic	<u> </u>		<u> </u>	1	<u> </u>	-	
	Trans-rectal	<u></u>	ļ			ļ		· · · · · · · · · · · · · · · · · · ·
	Trans-vaginal	ļ	ļ				<u> </u>	
	Trans-urethral	ļ				<u> </u>		-
	Trans-esoph. (non-Card.)		ļ		ļ	ļ		ļ
	Intra-luminal	ļ	<u> </u>					D.T.
	Other (Gynecological)	N	N	N	ļ	N	N	N
	Cardiac Adult	<u> </u>	ļ <u>.</u>		ļ	ļ		
Cardiac	Cardiac Pediatric	!		ļ		<u> </u>		ļ
	Trans-esoph. (Cardiac)	1	ļ		ļ		N N	
	Other (Fetal Heart)	N	N	N_		N	N	N
Peripheral	Peripheral vessel	<u> </u>		ļ	<u> </u>		-	<u> </u>
Vessel	Other (Carotid)	1	<u> </u>	<u> </u>	 	ļ	<u> </u>	
	Musculo-skel (conventional)	1	ļ		.			
	Musculo-skel (superficial)	<u> </u>		<u> </u>	<u> </u>		<u> </u>	1

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue), 3-D/4-D Imaging, Directional Angio Imaging,
Fetal Heart (Spatial Temporal Image Correlation), Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Real Time Biopsy, Dual
Previous submission: None

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Prescription Use (Per 21 CFR 801.109)

OTO(K) Number:	<u>K</u>
System: Philips !	Ultrasound HD11 Diagnostic Ultrasound System
Transducer:	3D6-2 (8500-2032-01) Curved Linear Transducer
Intended Use: Di	agnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation									
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD.	Color Doppler	Combined (Specify)	Other* (Specify)				
Ophthalmic	Ophthalmic							7				
	Fetal	N	N	N		N	N	N				
	Abdominal	N	N	N		N	N	N				
	Intra-operative (Specify)	I						 				
	Intra-operative (Neuro)		1				-	·········				
	Laparoscopic							 				
Fetal Imaging	Pediatric	N	N	N		N	N	N				
& Other	Small Organ (Scrotum,											
	Thyroid, Breast)							1				
	Neonatal Cephalic											
	Adult Cephalic			4		-						
•	Trans-rectal			•				10 3 1000				
e de la companya de l	Trans-vaginal											
	Trans-urethral						<u> </u>					
	Trans-esoph. (non-Card.)											
	Intra-luminal											
	Other (Gynecological)	N	N	N		N	N	N				
	Cardiac Adult:		-		•							
Cardiac	Cardiac Pediatric		,									
	Trans-esoph. (Cardiac)					•						
	Other (Fetal Heart)	N	N	N		N	N	N				
Peripheral	Peripheral vessel											
Vessel	Other (Carotid)											
	Musculo-skel (conventional)					-						
	Musculo-skel (superficial)							<u> </u>				
			r T									

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue), 3-D/4-D Imaging, Directional Angio Imaging,
Fetal Heart (Spatial Temporal Image Correlation), Color Power Angio

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Real Time Biopsy, Dual

Previous submission: Cleared on K034003

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043535

510(k) Number: <u>K</u>	-			
System: Philips Ultrasound HD11 Diagnostic Ult	rasound System			
Transducer: 3D9-3V (8500-1715-01) Curve	d Linear Transducer			
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:				

Clinical Applica	ion Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N	-	N	N	N
	Abdominal			·			-	
	Intra-operative (Specify)]					
	Intra-operative (Neuro)	<u> </u>						
	Laparoscopic	1						
Fetal Imaging	Pediatric							
& Other	Small Organ (Scrotum,	1					:	
	Thyroid, Breast)	<u> </u>		<u> </u>				
	Neonatal Cephalic		·		•			t 2.35,
	Adult Cephalic		<u> </u>					·
	Trans-rectal	<u></u>						
	Trans-vaginal	N	N	N		N	N	N .
	Trans-urethral							
	Trans-esoph. (non-Card.)						1:	
	Intra-luminal	<u> </u>						
	Other (Gynecological)	N	· N	N		N	. N	N ·
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal Heart)	N	N	N	·	N	N	N
Peripheral	Peripheral vessel							
Vessel	Other (Carotid)					,		
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue), 3-D/4-D Imaging, Directional Angio Imaging,
Fetal Heart (Spatial Temporal Image Correlation), Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Real Time Biopsy, Dual
Previous submission: Cleared as 3DIVT in K030455

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) 7
Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____